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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,911

04/20/2007

Morten Mernoe

18879-023US1

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EXAMINER

MEDWAY, SCOTT J

ART UNIT

PAPER NUMBER

3763

NOTIFICATION DATE

DELIVERY MODE

08/14/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,911	<b>Applicant(s)</b> MERNOE, MORTEN	
	<b>Examiner</b> SCOTT MEDWAY	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 50-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is the second Office Action based on the 10/587911 application filed 07/28/2006. Examiner acknowledges the reply filed 05/11/2009.

Claims 50-65 are currently pending and are considered below. Claims 58-65 are newly added.

#### ***Claim Objections***

1. Claim 58 is objected to because of the following informalities: the phrase “an adhesive layer coupled to the housing so as to affixed said housing to said skin of a user” contains one or more grammatical errors. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**3. Claims 50, 51 and 58-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Flaherty (U.S. Pat. 6,656,159 B2).**

Regarding claims 50 and 51, Flaherty discloses a disposable, wearable medicine dispensing device (see Fig. 1) comprising: a housing (20); means for attaching the housing to the skin such as an adhesive (col. 9, lines 36-38); a medicine container (32) disposed in the housing; a flexible piston rod (202, 606) shown in Fig. 4 to have an outer thread pattern; a ratchet wheel (502) having an inner thread pattern on a central

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aperture to mate with the outer thread pattern of the piston rod; a pivotable body (252); spring device (248) to bias the pivotable body; and actuation system comprising a thread member (508) and a battery powered actuator (80) to apply a tension force to the thread. A pawl member (216, 256) is additionally disposed on the pivotable body.

Regarding claims 59-62, the device is wearable on a user's body and dispenses insulin (col. 1, line 26) via a catheter and has user-interface buttons (120) and a display (110), is fully capable of being connected to a computer, and is fully capable of receiving user input based on new dosage rates in response to that input (col. 7, line 62 to col. 8, line 23).

### ***Claim Rejections - 35 USC § 103***

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**5. Claims 52, 53 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (U.S. Pat. 6,656,159 B2) in view of Hansen et al (U.S. Pub. 2002/0007154 A1, hereinafter "Hansen").**

Regarding claims 52, 53 and 63, Flaherty discloses the invention substantially as claimed except for the piston rod comprising rod segments hinged together where the outer thread pattern is on the rod segments and the segments are connected by hinges. Hansen discloses an injection device comprising a piston rod (1) which is actuated by a ratchet (3) and has threads on a portion of its segments (see Fig. 4), and where hinges

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formed of bendable material cause the segments to bend with respect to one another (see Fig. 4). It would have been obvious for one of ordinary skill in the art at the time of the invention to substitute the uniform rod of Flaherty with the segmented and flexible rod of Hansen so as to make a device performing the same function but being substantially smaller on the body, and having a piston that can bend so as to decrease the amount of space needed to operate it would be sufficient to accomplish this task.

**6. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (U.S. Pat. 6,656,159 B2) in view of Fogarty (U.S. Pat. 4,315,512).**

Regarding claim 54, the combination of Flaherty and Hansen renders substantially unpatentable the invention as claimed except for the bendable material of the piston being nylon. Fogarty discloses a piston in a medical device where the piston is made from nylon (col. 4, line 1). It would have been obvious for one of ordinary skill in the art at the time of the invention to use nylon as taught by Fogarty in the piston of Flaherty, since it is known and disclosed by Fogarty that nylon is a strong and flexible material, and its use would represent prompting the use of a known material on the basis of its suitability for a device's intended use.

**7. Claims 55 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (U.S. Pat. 6,656,159 B2) in view of Hansen et al (U.S. Pub. 2002/0007154 A1, hereinafter "Hansen"), further in view of Brown (U.S. Pat. 2,695,023).**

Regarding claims 55 and 64, the combination of Flaherty and Hansen renders substantially unpatentable the invention as claimed except for the outer thread pattern being a discontinuous thread pattern. Brown discloses a hypodermic syringe having detents (44, 45, 46, 47, 48) on an outer surface of the rod where the detents are situated in discontinuous groups. Since Brown discloses that the groups are for selectively adjusting the amount of material to be pushed by the piston rod from the syringe, it would have been obvious for one of ordinary skill in the art at the time of the invention to consider using a discontinuous thread pattern taught by Brown in the invention of Flaherty in view of Hansen so as to make a piston rod capable of being coupled to an actuator so as to provide a selective or incremental amount of material to be infused to the body.

**8. Claims 56, 57 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty (U.S. Pat. 6,656,159 B2) in view of Albisser et al (U.S. Pat. 6,752,789 B2, hereinafter "Albisser").**

Regarding claims 56 and 57, it is noted that Flaherty discloses the invention substantially as claimed except for the battery powered actuator being a solenoid. Albisser discloses a syringe plunger mechanism being powered by an actuator where the actuator is a solenoid (col. 3, lines 29-33). It would have been obvious for one of ordinary skill in the art at the time of the invention to implement a solenoid as a battery powered actuator as taught by Albisser in the device of Flaherty, since solenoids are

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well-known in the art of battery-powered syringe mechanisms to allow for controlled or selective infusion of drugs.

### ***Response to Arguments***

9. Applicant's arguments with respect to claim 50 have been considered but are moot in view of the new ground(s) of rejection.

In response to Applicant's argument that the lead screw of Flaherty is not "flexible", Examiner disagrees. Since the lead screw of Flaherty is made from plastic (see col. 10, line 53), it inherently has some flexibility. Also, since the piston rod of Applicant's invention is disclosed to be plastic (Specification, page 11) having at least some portions having rigidity suitable to exert pressure on a piston (see Specification, page 11), Examiner interprets the lead screw of Flaherty to be fully capable of performing a similar use since the lead screw of Flaherty is also plastic and has at least some portions providing rigidity suitable to exert pressure on a piston.

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCOTT MEDWAY whose telephone number is (571) 270-3656. The examiner can normally be reached on Monday through Friday, 7:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott J. Medway/  
Examiner, AU 3763  
08/11/2009

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763